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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Christopher D. Wiegel

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WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP
111 MONUMENT CIRCLE, SUITE 3700
INDIANAPOLIS, IN 46204-5137

EXAMINER

TOWA, RENE T

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

6

Office Action Summary	Application No. 10/811,268	Applicant(s) WIEGEL, CHRISTOPHER D.	
	Examiner Rene Towa	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Objections

1. Claim 14 is objected to because of the following informalities:

The limitations "an area of contact between the expression surface and the body part" appear to make a positive body recitation. It is suggested that the Applicant amend the claim to include --adapted to contact-- or --configured to contact--.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3, 6-20 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitchen (US Patent No. 5,014,718).

In regards to claim 1, Mitchen disclose(s) a bodily fluid sampling device 10, comprising:

an incision forming device 13 to form an incision in a finger; and

an expression cap 14 defining an opening through which the incision forming device 13 forms an incision, the expression cap 14 having an expression surface

Art Unit: 3736

capable of expressing fluid from the incision, the expression surface having at least two opposing compression surfaces with a negative sigmoidal shape capable of enhancing expression of body fluid from the incision, the expression cap 14 defining a relief notch between the compression surfaces, the relief notch being sized to receive the finger to permit the compression surfaces to first contact the finger when the expression surface is pressed against the finger (see figs. 2-4; column 2/lines 45-49 & 56-66).

In regards to claim 2, Mitchen disclose(s) a bodily fluid sampling device 10 wherein: the expression cap 14 includes a support portion 12 and an expression portion 14 detachably coupled to the support portion, wherein the expression portion is detachable from the support portion to allow cleaning of the expression portion (see figs. 2-4).

In regards to claim 3, Mitchen disclose(s) a bodily fluid sampling device 10 further comprising a testing device 19 disposed in the expression cap 14 for analyzing the fluid from the incision (see figs. 2-4; column 3/lines 4-16).

In regards to claim 6, Mitchen disclose(s) a bodily fluid sampling device 10 wherein the relief notch extends on opposite sides of the opening.

In regards to claim 7, Mitchen disclose(s) a bodily fluid sampling device 10 further comprising a device body 19 coupled to the expression cap 14 (see figs. 2-4).

In regards to claim 8, Mitchen disclose(s) a bodily fluid sampling device 10 wherein the expression cap 14 is removable from the device body (see figs. 2-4).

In regards to claim 9, Mitchen disclose(s) a bodily fluid sampling device 10, comprising:

means for forming an incision 13 in a body part; and
an expression cap 14 defining an opening through which the means for forming the incision 13 forms the incision, the expression cap 14 having an expression surface, the expression surface defining a relief notch, wherein the expression surface is shaped to apply a generally even force against the body part when expressing body fluid from the incision (see figs. 2-4; column 2/lines 45-49 & 56-66).

In regards to claim 10, Mitchen disclose(s) a bodily fluid sampling device 10 wherein the expression surface has a negative sigmoid shape (see figs. 2-4).

In regards to claim 11, Mitchen disclose(s) a bodily fluid sampling device 10 wherein the expression surface has a saddle shape (see figs. 2-4).

In regards to claim 12, Mitchen disclose(s) a bodily fluid sampling device 10 wherein the relief notch extends across the opening (see figs. 2-4).

In regards to claim 13, Mitchen disclose(s) a bodily fluid sampling device 10 wherein the expression cap 14 has a generally cylindrical shape (see figs. 2-4).

In regards to claim 14, Mitchen disclose(s) a bodily fluid sampling device wherein an area of contact between the expression surface and the body part has a surface area between about 0.2 to 0.6 square inches (see column 5/lines 10-16).

In regards to claim 15, Mitchen disclose(s) a method, comprising:
providing a sampling device 10 that has an expression surface with at least two opposing compression surfaces that have a negative sigmoidal shape and a relief notch defined between the compression surfaces that is shaped to generally conform to a body part;

placing the expression surface against the body part with at least a portion of the body part received in the relief notch;

forming an incision in the body part with the sampling device 10; and

expressing body fluid from the incision by exerting pressure between the body part and the expression surface (see figs. 2-4; column 3/lines 4-16; column 4/line 58 to column 5/line 5; column 5/lines 10-16 & 25-30).

In regards to claim 16, Mitchen disclose(s) a method, wherein the expression surface has a negative sigmoid shape (see figs. 2-4).

In regards to claim 17, Mitchen disclose(s) a method, further comprising analyzing the body fluid with the sampling device 10 (see column 3/lines 12-16).

In regards to claim 18, Mitchen disclose(s) a method, further comprising keeping the sampling device 10 in place against the body part during said forming and said expressing (see column 3/lines 4-7).

In regards to claim 19, Mitchen disclose(s) a method, wherein said placing the expression surface against the body part occurs before said expressing the body fluid (see column 4/line 58 to column 5/line 5).

In regards to claim 20, Mitchen disclose(s) a method, wherein said expressing includes pressing the body part against the expression surface (see column 4/line 58 to column 5/line 5).

In regards to claim 22, Mitchen disclose(s) a method, wherein:
the sampling device 10 includes an incision forming device 13;
the expression surface defines an opening; and

Art Unit: 3736

said forming the incision includes forming the incision through the opening with the incision forming device 13 (see figs. 2-4; column 3/lines 4-16; column 4/line 58 to column 5/line 5; column 5/lines 10-16 & 25-30).

4. Claims 1-2, 4-13, 15-17, 19 and 21-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Moerman (US Patent No. 6,706,049).

In regards to claim 1, Moerman disclose(s) a bodily fluid sampling device (10, 80), comprising:

an incision forming device 30 to form an incision in a finger; and
an expression cap (16, 85) defining an opening (18, 92) through which the incision forming device 30 forms an incision, the expression cap (16, 85) having an expression surface (22, 88) to express fluid from the incision, the expression surface (22, 88) having at least two opposing compression surfaces (24, 88B) with a negative sigmoidal shape to enhance expression of body fluid from the incision, the expression cap (16, 85) defining a relief notch (26, 87) between the compression surfaces (24, 88B), the relief notch (26, 87) being sized to receive the finger to permit the compression surfaces (24, 88B) to first contact the finger when the expression surface (22, 88) is pressed against the finger (see figs. 1, 3B, 4A-B & 10; column 4/lines 39-42 & 43-48; column 5/lines 16-26, 28-33, 35-38 & 41-44; column 8/lines 32-38 & 54-59; column 8/line 60 to column 9/line 9; column 9/lines 19-28 & 31-36).

In regards to claim 2, Moerman disclose(s) a bodily fluid sampling device (10, 80) wherein: the expression cap (16, 85) includes a support portion 12 and an expression portion (14, 81) detachably coupled to the support portion, wherein the expression

Art Unit: 3736

portion 14 is detachable from the support portion to allow cleaning of the expression portion 14 (see fig. 1; column 4/lines 49-52 & 58-61; column 8/lines 38-45).

In regards to claim 4, Moerman disclose(s) a bodily fluid sampling device (10, 80) wherein the expression surface (22, 88) is textured to enhance expression of fluid from the incision (see fig. 3B; column 6/lines 22-36 & 54-58; column 9/lines 31-36).

In regards to claim 5, Moerman disclose(s) a bodily fluid sampling device (10, 80) wherein the expression surface (22, 88) defines a plurality of ridges (see fig. 3B).

In regards to claim 6, Moerman disclose(s) a bodily fluid sampling device (10, 80) wherein the relief notch (26, 87) extends on opposite sides of the opening (18, 92) (see figs. 4A & 10).

In regards to claim 7, Moerman disclose(s) a bodily fluid sampling device (10, 80) further comprising a device body 12 coupled to the expression cap (16, 85) (see figs. 1 & 10).

In regards to claim 8, Moerman disclose(s) a bodily fluid sampling device (10, 80) wherein the expression cap (16, 85) is removable from the device body 12 (see fig. 1; column 4/lines 49-52 & 58-61; column 8/lines 38-45).

In regards to claim 9, Moerman disclose(s) a bodily fluid sampling device (10, 80), comprising:

means for forming an incision 30 in a body part; and

an expression cap (16, 85) defining an opening (18, 92) through which the means for forming the incision forms the incision, the expression cap (16, 85) having an expression surface (22, 88), the expression surface (22, 88) defining a relief notch (26,

Art Unit: 3736

87), wherein the expression surface (22, 88) is capable of applying a generally even force against the body part when expressing body fluid from the incision (see figs. 1, 3B, 4A-B & 10; column 4/lines 39-42 & 43-48; column 5/lines 16-26, 28-33, 35-38 & 41-44; column 8/lines 32-38 & 54-59; column 8/line 60 to column 9/line 9; column 9/lines 19-28 & 31-36).

In regards to claim 10, Moerman disclose(s) a bodily fluid sampling device (10, 80) wherein the expression surface (22, 88) has a negative sigmoid shape (see figs. 4A & 10).

In regards to claim 11, Moerman disclose(s) a bodily fluid sampling device (10, 80) wherein the expression surface (22, 88) has a saddle shape (see figs. 4A & 10).

In regards to claim 12, Moerman disclose(s) a bodily fluid sampling device (10, 80) wherein the relief notch (26, 87) extends across the opening (18, 92) (see figs. 4A & 10).

In regards to claim 13, Moerman disclose(s) a bodily fluid sampling device (10, 80) wherein the expression cap (16, 85) has a generally cylindrical shape (see figs. 1 & 10).

In regards to claim 15, Moerman disclose(s) a method, comprising:

providing a sampling device (10, 80) that has an expression surface (22, 88) with at least two opposing compression surfaces (24, 88B) that have a negative sigmoidal shape and a relief notch (26, 87) defined between the compression surfaces (24, 88B) that is shaped to generally conform to a body part;

Art Unit: 3736

placing the expression surface (22, 88) against the body part with at least a portion of the body part received in the relief notch (26, 87);

forming an incision in the body part with the sampling device (10, 80); and
expressing body fluid from the incision by exerting pressure between the body part and the expression surface (22, 88) (see column 7/lines 1-17).

In regards to claim 16, Moerman disclose(s) a method, wherein the expression surface (22, 88) has a negative sigmoid shape (see figs. 4A & 10).

In regards to claim 17, Moerman disclose(s) a method, further comprising analyzing the body fluid with the sampling device (10, 80) (see column 4/lines 39-42).

In regards to claim 19, Moerman disclose(s) a method, wherein said placing the expression surface (22, 88) against the body part occurs before said expressing the body fluid (see column 7/lines 1-17).

In regards to claim 21, Moerman disclose(s) a method, wherein said expressing includes pressing the expression surface (22, 88) against the body part (see fig. 9).

In regards to claim 22, Moerman disclose(s) a method, wherein:
the sampling device (10, 80) includes an incision forming device 30;
the expression surface (22, 88) defines an opening (18, 92); and
said forming the incision includes forming the incision through the opening (18, 92) with the incision forming device (see column 7/lines 1-17).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 5,569,286 to Peckham et al. discloses a lancet assembly

US Patent No. 5,843,036 to Olive et al. discloses non-dosing cartridge for an injection device.

US Patent No. 5,324,303 to Strong et al. discloses a combined lancet and multi-function cap and lancet injector for use therewith.

US Patent No. 6,197,040 to LeVaughn et al. discloses lancing device having a releasable connector.

US Patent No. 5,383,885 to Bland discloses a blood collection and testing device.

US Patent No. 5,709,699 to Warner discloses a blood collection and testing device.

US Patent No. 4,484,910 to Sarnoff et al. discloses a dual mode automatic injector.

US Patent No. 4,635,633 to Hufnagle discloses a combination sterile pad support and lancet.

US Patent No. 5,318,584 to Lange et al. discloses a blood lancet device for withdrawing blood for diagnostic purposes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

Art Unit: 3736

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTT


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